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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,078	12/18/2006	Kenneth D. Somers	0113019.00152US3	2612
24395	7590	02/02/2009		
WILMERHALE/DC 1875 PENNSYLVANIA AVE., NW WASHINGTON, DC 20006			EXAMINER SANG, HONG	
			ART UNIT 1643	PAPER NUMBER
			NOTIFICATION DATE 02/02/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/569,078	SOMERS ET AL.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Somers et al.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- | | |
|------------|--|
| Group I, | claim(s) 1-15, 18-29, and 51-58, drawn in part to a method for aiding a diagnosis of head and neck squamous cell carcinoma in a patient, comprising detecting at least one protein biomarker in a body fluid obtained from the patient, wherein the biomarker is detected by mass spectrometry. |
| Group II, | claim(s) 1-10, 16-24, 30, 31, 51, and 52, drawn in part to a method for aiding a diagnosis of head and neck squamous cell carcinoma in a patient, comprising detecting at least one protein biomarker in a body fluid obtained from the patient, wherein the biomarker is detected by immunoassay. |
| Group III, | claim(s) s 32-45, drawn to a kit comprising a substrate comprising an adsorbent attached thereto, wherein the adsorbent is capable of retaining at least one protein biomarker. |
| Group IV, | claim 46, drawn to a method of using a plurality of classifier to make a probable diagnosis of head and neck squamous cell carcinoma or a negative diagnosis. |
| Group V, | claim(s) 47-50, drawn to a computer program medium storing computer instruction therein for instructing a computer to perform a computer-implemented process of aiding a diagnosis of benign prostate hyperplasia or prostate cancer. |

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

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corresponding special technical features for the following reasons: the special technical feature linking the Groups I-V appears to be a kit comprising a substrate comprising an adsorbent attached thereto, wherein the adsorbent is capable of retaining at least one protein biomarker selected from the biomarkers listed in claim 39 (see claim 39). The substrate of claim 32 cannot be a special technical feature under PCT Rule 13.2 because it is shown in the prior art. Merchant et al. (Electrophoresis 2000, 21, 1164-1167) teach various SELDI ProteinChip surfaces used in SELDI applications, wherein chemical surfaces arrays are derivatized with classic chromatographic separation moieties such as reverse phase, ion exchange, immobilized metal affinity capture (IMAC) and mixed mode media (see page 1165, column 2, last paragraph, and Figure 1). Merchant et al. teach that such surfaces with broad binding properties, are typically used in protein profiling and biomarker discovery, where large panels of proteins are compared (e.g., from diseased vs. normal samples) with the goal of pinpointing differentially expressed elements (see page 1165, column 2, last paragraph). The SELDI ProteinChip surfaces taught by Merchant are capable of retaining the instantly recited biomarkers (see page 1173, Figure 10). Furthermore, WO 03/072710 (Pub. Date: 9/4/2003, earliest effective filing date: 2/21/2002) teach a kit comprising an adsorbent attached to a substrate, wherein the adsorbent is suitable for retaining the markers including marker EP11, i.e. 14696 ± 81 Da (see claim 45), which read on the instant biomarker 14687 ± 29.4 Dalton. As such the technical feature linking the inventions is not novel and does not provide contribution over the prior art. Therefore, unity of invention is lacking and the inventions are deemed to be separate.

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3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (a) 2778±5.6, 2951±5.9, 3772±7.5, 3888±7.8, 4181±8.4, 4464±8.9, 5064±10.1, 5078±10.2, 5242±10.5, 5335 ±10.7, 5363 ±10.7, 5544±11.1, 5905±11.8, 5920 ±11.8, 6110±12.2, 7764±15.5, 7805±15.6, 7830±15.7, 7920±15.8, 7971 ±15.9, 8928±17.9, 9094±18.1, 9134±18.3, 9181±18.4, 9287±18.6, 9416±18.8, 10264±20.5, 10843±21.7, 11722±23.4, 11922±23.8, 13350±26.7, 13881±27.8, 14687±29.4, and 15139±30.3 Daltons.
- (b) blood serum, seminal fluid, seminal plasma, saliva, blood, lymph fluid, lung/bronchial washes, mucus, feces, nipple secretions, sputum, tears, or urine.
- (c) metal chelate adsorbent, adsorbent comprises a cationic group, substrate comprises a plurality of different types of adsorbent, antibody adsorbent

Applicant is required, in reply to this action, **to elect a single biomarker or a combination of biomarkers from Group (a)** (if applicant elects a combination of biomarkers, applicant must specify the number and the molecular weight of the biomarkers, for example: 3 biomarkers, 5064 ± 10.1, 13881 ± 27.8, and 15139 ± 30.3), **a single body fluid sample from Group (b), and a single adsorbent from Group (c)** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any

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claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Different biomarkers listed in group (a): 1-45 and 47-58

Samples listed in group (b): claims 18, and 19

Adsorbent listed in group (c): claims 34-37 and 41-44

The following claim(s) are generic: 46.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features, and/or the species are known in the art.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

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are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643
1/23/09